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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,380	02/11/2005	Masaharu Maruo	SAEG124.003APC	4846
20995 7590 08/10/2009 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614				
EXAMINER NOGUEROLA, ALEXANDER STEPHAN				
ART UNIT		PAPER NUMBER		
1795				
NOTIFICATION DATE		DELIVERY MODE		
08/10/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

### Office Action Summary

**Application No.**

10/524,380

**Applicant(s)**

MARUO ET AL.

**Examiner**

ALEX NOGUEROLA

**Art Unit**

1795

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7/27/2009 (RCE).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10, 11, 13 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10, 11, 13, and 18-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

1. Applicant's amendment of July 27, 2009 does not render the application allowable. As described in the rejections below Feldman still meets the limitations of the claims.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 10, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Feldman et al. US 6,299,757 B1 ("Feldman").

Addressing claim 10, Feldman discloses a biosensor (abstract) comprising:  
in its tip portion, an electrically insulating substrate (500 or 579) and a cover sheet (508 or 583) facing each other with a space in between and a spacer sheet (504 or 581) somewhere therebetween (Figures 18A-18C or Figures 22A-22C ; and a reaction part having an oxidoreductase in a holding space formed by the substrate, the cover sheet and the spacer sheet end (col. 32:65 – col. 33:15 and col. 38:07 –

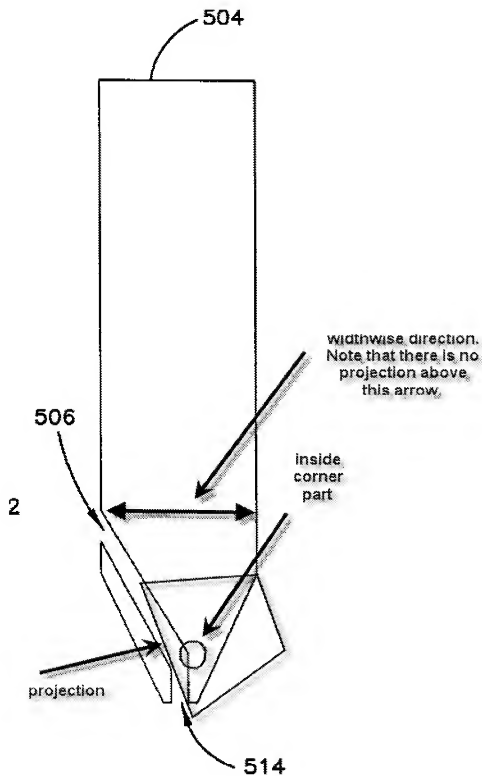
col. 39:09);

the liquid sample being delivered from the tip of the sensor into the holding space by capillary action (col. 32:07-13 and col. 34:37-42, and an electrochemical change caused by an enzyme reaction between the liquid sample and the reaction part being detected using an electrode set having a working electrode and a counter electrode (col. 38:07 – col. 39:15);

the biosensor being provided with a projection at only one side of the spacer in the widthwise direction sheet end in the holding space with the projection extending toward the end of the biosensor (see Figures 18B and 22B reproduced below with projection identified. Note that projection(s) only occur at only one side of the double-headed arrow, which represents the widthwise direction.);

the spacer sheet being composed of one sheet (the Examiner construes “composed” to have the same meaning as – comprising --, this is, he does not “composed” to be “closed” language such as -- consisting of -- or consisting essentially of --); and

the electrode being disposed on the substrate (Figures 18A, 18C, 22A, and 22C).



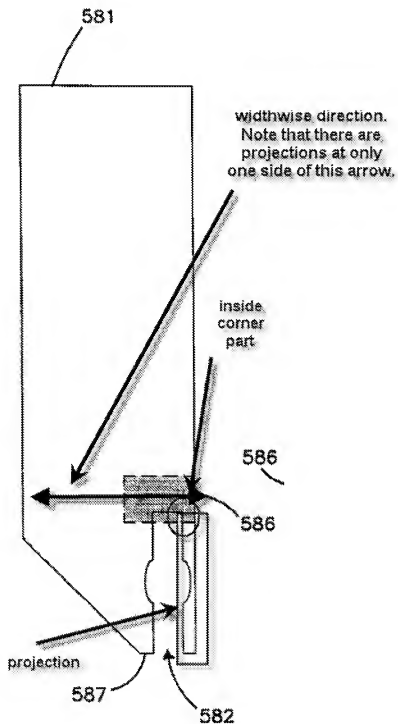


FIG. 22B

Addressing claim 11, see Figure 22B reproduced above with the inside corner part Identified. By being located beyond the curved portions of the projection the inside corner part enlarges the capacity of the holding space.

Addressing claim 13, for the additional limitations of this claim see in Feldman col. 38:07 – col. 39:15; col. 23:50-58; and col. 11:35-49 (note lactate).

Addressing claim 18, for the additional limitations of this claim see in Feldman Figures 18A, 18C, 22A, and 22C.

Addressing claim 19, for the additional limitations of this claim see in Feldman Figures 18A-18C and 22A-22C (compare with Applicant's figures, which require only three linear, perpendicular sides for the sensor).

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 19 requires the substrate to be formed in a rectangular shape. To the extent that this new claim requires the substrate to be defined by four perpendicular sides "rectangular shape" is not supported as the figures clearly show one side of the biosensor having a semicircular shape.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the



invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman in view of Bhullar US 6,447,657 B1 ("Bhullar")

Feldman discloses

a biosensor (abstract) comprising:

in its tip portion, an electrically insulating substrate (500 or 579) and a cover sheet (508 or 583) facing each other with a space in between and a spacer sheet (504 or 581) somewhere therebetween (Figures 18A-18C or Figures 22A-22C ; and a reaction part having an oxidoreductase in a holding space formed by the substrate, the cover sheet and the spacer sheet end (col. 32:65 – col. 33:15 and col. 38:07 – col. 39:09);

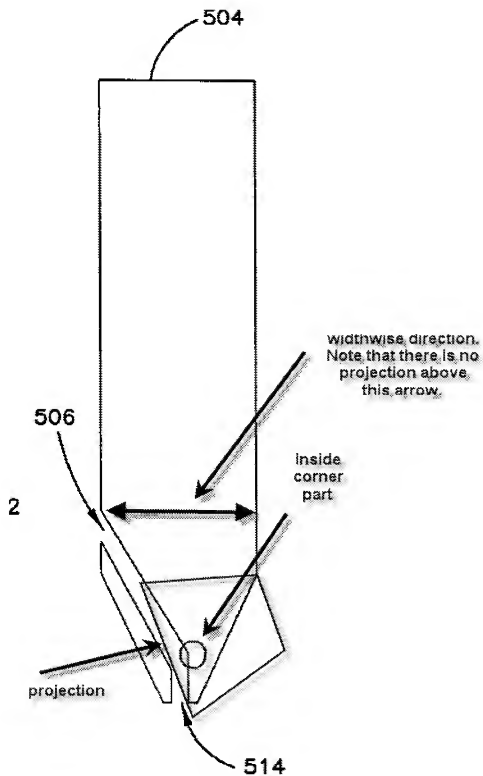
the liquid sample being delivered from the tip of the sensor into the holding space by capillary action (col. 32:07-13 and col. 34:37-42, and an electrochemical change caused by an enzyme reaction between the liquid sample and the reaction part being

detected using an electrode set having a working electrode and a counter electrode (col. 38:07 – col. 39:15); and

the biosensor being provided with a projection at only one side of the spacer in the widthwise direction sheet end in the holding space with the projection extending toward the end of the biosensor (see Figures 18B and 22B reproduced below with projection identified. Note that projection(s) only occur at only one side of the double-headed arrow, which represents the widthwise direction.);

the space sheet being composed of one sheet (the Examiner construes “composed” to have the same meaning as – comprising --, this is, he does not “composed” to be “closed” language such as -- consisting of -- or consisting essentially of --); and

the electrode being disposed on the substrate (Figures 18A, 18C, 22A, and 22C).



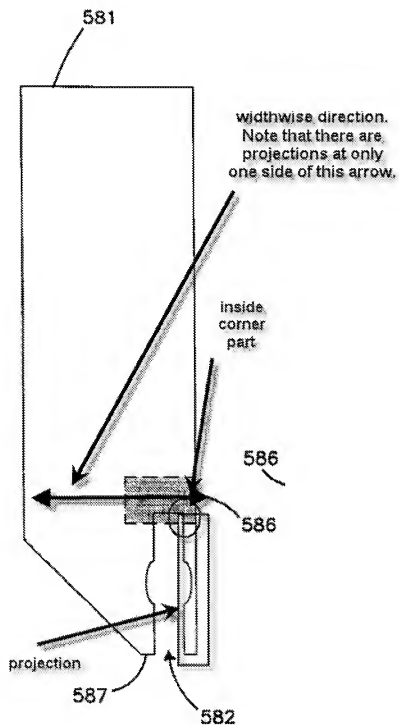


FIG. 22B

Figures 18A-18C and 22A-22C only show a tip portion that is formed approximately in a semicircular shape. However, as shown by Figures 3 and 10 of Bhullar at the time of the invention having a tip portion of an electrochemical test strip sensor be formed in a semicircular shape was a known alternative to having the tip formed approximately in a triangular shape. Thus, if the choice of tip shape is not actually just a design choice it is at least substitution of one known element for another to provide predictable results.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/  
Primary Examiner, Art Unit 1795  
August 3, 2009